

OPTN/UNOS Data Advisory Committee

Report to the Board of Directors

December 1-2, 2015

Richmond, VA

Charlie Alexander, RN, MSN, MBA, Chair

Joseph Kim, MD, PhD, MHS, FRCPC, Vice Chair

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This report reflects the work of the OPTN/UNOS Data Advisory Committee during the May 2015 through November 2015 period.

Action Items

1. Data Release Policy Revisions

Public Comment: [August 14 – October 14, 2015](#)

The Final Rule requires the OPTN Contractor to release to the public “data needed for bona fide research or analysis purposes,” and to “respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.” The OPTN/UNOS data release policy, which governs the data that may be released to the public and the process for doing so, is more restrictive than the Final Rule: it restricts the release of institution-identified data, even though the Final Rule requires the OPTN to release data to allow the public to assess individual transplant programs, and for other purposes. This proposal amends policy to ensure that it is consistent with the Final Rule.

The Committee considered and addressed public comment received on its proposed policy language. After discussion, the Committee voted (8 yes, 0 no, 0 abstentions) to recommend the following new and modified policies for consideration by the Board of Directors:

Resolved, that modifications to Policies 19: Data Release; 19.1: Mailing Lists; 19.2: Composite Demographic Data; 19.3: Organ Center Data; 19.4: Sharing Arrangements; 19.5: Members; 19.6: Public Release of Transplant Hospital and OPO Activity; 19.7: Release of Transplant Hospital Specific Data; 19.8: Review of Member Specific Data; 19.9: Access to Recipient Outcomes Data; 19.10: Information before the Board of Directors; 19.11: Release of Human Leukocyte Antigen (HLA) Type of a Recipient’s Prior Donor; 19.12: Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier; 19.13: Access to Database; 19.14: Transfer of Information; 19.15: Specific Projects; 19.16: Public Use, Presentations, and Publications; and 19.17: Committee Access to Data, as set forth in Exhibit A, are hereby approved, effective March 1, 2015.

Other Committee Work

2. OPO Metrics

DAC OPO Metrics Subcommittee members worked with members of the MPSC, the OPO Committee, the Association of Organ Procurement Organizations (AOPO) and the SRTR to review OPO metrics and measures. AOPO CEOs met at a recent meeting and voted unanimously to support the following efforts:

- Eliminate the DCD, ECD, SCD yield measure and replace them with the SRTR observed to expected yield model currently used by MPSC to evaluate yield for OPOs.

- Do not propose modifications to the research metric that is currently used (but plan to do so in the future).
- Eliminate the conversion rate measure because it is based on the subjective definition imminent and eligible donors. The measure is subjective because it depends upon self-reported data, it is difficult to audit and interpret, and it is subject to wide variability across DSAs.

In addition to eliminating the current conversion rate measure, the AOPO CEOs voted to support work on a donation rate measure, which measures volumes, to create incentives to increase donor volumes. The starting point should be measuring donors per 1,000 in-hospital deaths, as this measure is auditable and there are external data sets that can validate whether an OPO is reporting all in-hospital deaths in its DSA.

The UNOS Research Department is now performing a feasibility study, based on an OPTN contract modification, to determine whether these data could be collected in a standardized way. Some members of the DAC OPO Metrics Work Group, as well as some members of the MPSC and OPO Committee, will be part of the task force providing field knowledge for this study. The members of the task force will keep the DAC up to date with the progress of the feasibility study.

3. Developing an evidence-based decision-making strategy for OPTN registry data elements

In May, UNOS staff presented a proposed process for reviewing new and existing data elements. Proposals to modify, remove, or collect additional data elements need to be sponsored by an OPTN/UNOS committee, and earn project approval from the Policy Oversight Committee (POC) and Executive Committee. The proposal would be developed by the sponsoring committee, with help from the DAC if requested, and would eventually be reviewed by DAC as an additional step in the current policy development process. The DAC will create standards for reviewing the data collection proposals, particularly to ensure that the proposals are supported by ample evidence. Similar to how the POC makes recommendations about whether public comment proposals have met the OPTN's standards for policy development, the DAC would make a recommendation to the Policy Oversight Committee and Executive Committee about the proposal's readiness to move forward for public comment.

The next steps for the DAC are to create a review process, review the current Principles of Data Collection, create standards for evidence required to support proposals for data collection, and create standards for defining data elements that are reported to the OPTN.

Meeting Summaries

The committee held meetings on the following dates:

- May 20, 2015
- June 17, 2015
- October 21, 2015

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=58>

OPTN/UNOS Data Advisory Committee

Proposal to Revise OPTN/UNOS Data Release Policies

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Proposal to Revise OPTN/UNOS Data Release Policies

Executive Summary

Current OPTN/UNOS policies restrict the release of organ procurement organization (OPO) and hospital identified data. The OPTN Final Rule (the Final Rule) requires the OPTN to release data in response to “reasonable requests from the public for data needed for bona fide research or analysis purposes” and “reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”¹ The Health Resources and Services Administration (HRSA) clarified that this portion of the Final Rule applies to release of data identified by transplant hospital or OPO, and therefore OPTN/UNOS policy is not consistent with the Final Rule.

This proposal revises the OPTN/UNOS policy to better align with the Final Rule by removing restrictions on the release of OPTN data. This will allow the OPTN contractor to release more data than are currently released, including any non-confidential data by institution (e.g., data identifiable by transplant hospital, histocompatibility lab, or OPO).

¹ Organ Procurement and Transplantation Network Final Rule, 42 CFR §121.11. (2000, March 16). http://www.ecfr.gov/cgi-bin/text-idx?SID=35e138c2435e0872c2c9d837f97ceede&mc=true&node=se42.1.121_111&rqn=div8

Proposal to Revise OPTN/UNOS Data Release Policies

Affected Policies: Policies 19: Data Release; 19.1: Mailing Lists; 19.2: Composite Demographic Data; 19.3: Organ Center Data; 19.4: Sharing Arrangements; 19.5: Members; 19.6: Public Release of Transplant Hospital and OPO Activity; 19.7: Release of Transplant Hospital Specific Data; 19.8: Review of Member Specific Data; 19.9: Access to Recipient Outcomes Data; 19.10: Information before the Board of Directors; 19.11: Release of Human Leukocyte Antigen (HLA) Type of a Recipient's Prior Donor; 19.12: Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier; 19.13: Access to Database; 19.14: Transfer of Information; 19.15: Specific Projects; 19.16: Public Use, Presentations, and Publications; and 19.17: Committee Access to Data

Sponsoring Committee: OPTN/UNOS Data Advisory Committee

Public Comment Period: August 14, 2015 – October 14, 2015

What problem will this proposal solve?

Current OPTN/UNOS policy restricts the release of organ procurement organization (OPO) and hospital identified data. The OPTN Final Rule (the Final Rule) requires the OPTN to release data in response to “reasonable requests from the public for data needed for bona fide research or analysis purposes” and “reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”² The Health Resources and Services Administration (HRSA) clarified that this portion of the Final Rule applies to release of data identified by transplant hospital or OPO, and therefore OPTN policy is not consistent with the Final Rule.

Why should you support this proposal?

The proposed solution ensures that OPTN policies and processes remain consistent with the Final Rule, and permits the OPTN to release data that will allow the public to perform research and independently evaluate OPTN members.

How was this proposal developed?

The OPTN/UNOS Policy Oversight Committee initially sought to revise the OPTN/UNOS data release policy in 2012, but ultimately tabled the proposal due to a lack of consensus in the community.³ During the February 10, 2015 Data Advisory Committee (DAC) meeting, HRSA explained that the current OPTN/UNOS data release policy is not consistent with the Final Rule because it imposes more restrictions on the release of hospital, and OPO identifiable data than is allowed by the Final Rule, and must be revised. In response, UNOS staff, DAC members, the Scientific Registry of Transplant Recipients (SRTR) Contractor, and HRSA reviewed the current data release policy to identify areas that are inconsistent with the requirements of the Final Rule. DAC's Data Release Policy Subcommittee met

² Organ Procurement and Transplantation Network Final Rule, 42 CFR §121.11. ECFR — Code of Federal Regulations. (2000, March 16). Retrieved October 28, 2015, from <http://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5>

³ http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_310.pdf

multiple times by phone during the spring of 2015 to achieve consensus on recommended revisions to policy.

DAC developed language that removed the restrictions for releasing transplant hospital and OPO identifiable data. It also included a detailed table explaining when it is appropriate to release person-identifiable data, and to whom such data can be released. Other provisions included restrictions on the release of confidential information.

Based on feedback provided by HRSA, DAC elected to propose policy that simply confirms that the OPTN will release OPTN data according to the Final Rule and other applicable laws and regulations. The remainder of the data release process will be maintained in standard operating procedures that will be available to the public. DAC discussed and voted on the final proposed policy language on its June 17, 2015 conference call and voted to send the proposal for public comment.

How well does this proposal address the problem statement?

This proposal revises the OPTN/UNOS data release policies to remove restrictions not permitted by the Final Rule. The Final Rule requires the OPTN contractor to “Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes.”⁴ The new policy allows the OPTN Contractor to release more data than are currently released, including non-confidential data by institution. Examples of data that are not releasable under current policy, but would be releasable under the proposed policy, include de-identified patient-level Standard Analysis and Research (STAR) files that include transplant hospital and OPO identifiers.⁵

HRSA representatives and the U.S. Department of Health and Human Services (DHHS) legal counsel reviewed the proposed policy language and determined that the proposed changes are consistent with the requirements of the Final Rule. Furthermore, the protections for person-identified and person-identifiable data remain intact, as other laws, such as the Health Insurance Portability and Accountability Act (HIPAA)⁶ and the Privacy Act⁷, impose restrictions on the OPTN’s ability to release such data.

As allowed by the Final Rule, UNOS staff in the Research Department will still evaluate data requests for reasonableness, but the process for doing so will not reside in OPTN policy. For transparency, the OPTN will make the process it follows for processing data requests publicly available. For data requests for transplant hospital or OPO identified data, the OPTN Contractor will review to determine whether the request is for data that are confidential or peer-reviewed. If so, the request is not “reasonable” and the OPTN will not release the requested data. If the request is for data that are not confidential or peer-reviewed, the OPTN staff will determine the reasonableness of the request based on the resources required to fulfill the request. If the request is for something similar to a standard STAR file, the request will be filled immediately. If the request is for more customized data, such as a customized STAR file, the request will be filled based on staff time and availability. Lastly, if the request requires complicated customization of a data file, the request may be filled dependent on staff availability and the requestor’s willingness to pay a reasonable fee.

Releasing data by institution could result in publication of analyses that reflect poorly on transplant hospitals and OPOs and whose quality will be beyond the control of the OPTN. This is a concern to some members; however, providing this type of protection to institutions is not under the purview of the OPTN. Additionally, releasing these data can make it easier to evaluate any misinterpretations of data. Also,

⁴ Final Rule 121.11(b)(vi)

⁵ For more information on STAR files, visit http://optn.transplant.hrsa.gov/converge/data/request_main.asp?refer=true

⁶ Pub. L. 104-191, available at <http://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html>

⁷ Pub. L. 93-579, available at <http://www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg1896.pdf>

releasing this information may result in research that provides a great benefit to patients, OPTN members, and policymakers.

Removing restrictions on the release of hospital and OPO identified OPTN data could also have the unintended effect of making patient-level datasets (e.g., STAR files) more easily identifiable for certain small populations, such as pediatric patients or intestinal transplant recipients. The OPTN Contractor's standard operating procedure requiring that all persons who receive patient-level data sign a data use agreement, which is a contract in which they agree not to attempt to identify patients in the dataset mitigates this concern.

The process for release of patient-identified data (e.g., patient name or Social Security Number) will not change as a result of this proposal. The Final Rule states, "Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed."⁸ The OPTN Contractor may therefore release patient-identified data, but the OPTN Contractor fulfills requests for these data only after obtaining approval from HRSA.

After reviewing the Final Rule and all applicable laws and regulations, the DAC is confident that the proposed changes will align OPTN policies with the Final Rule, make data more readily available to the public and to researchers, and maintain confidentiality protections.

Was this proposal changed in response to public comment?

DAC received a number of comments and questions in response to this proposal. The comments received for this proposal are on the Organ Procurement and Transplantation Network (OPTN) website at <http://optn.transplant.hrsa.gov/governance/public-comment/>. On October 21, 2015, DAC determined that the proposal does not require changes, and it should be presented to the Board of Directors using the same language that was distributed for public comment.

- **What defines a "reasonable" request for data?**

For data requests for transplant center-, OPO-, or histocompatibility laboratory-identified data, the OPTN Contractor (UNOS staff) will evaluate reasonableness consistently. First, staff will determine whether the request seeks confidential or peer reviewed data. If so, the request is not "reasonable" and these data will not be released. If not, UNOS staff will evaluate the size of the request. If the request is for something similar to a standard STAR file (containing institution-identified data) the request will be filled immediately. If the request is for more customized data, such as a customized STAR file, the request will be filled based on staff time and availability. Lastly, if the request requires complicated customization of a data file, the request may be filled dependent on staff availability and the requestor's willingness to pay a reasonable fee.

The entire process for reviewing data requests is documented in the Standard Operating Procedures for Review of OPTN Data Requests, which is included in **Appendix A**.

⁸ Final Rule 121.11(b)(v)

- **Who at OPTN will perform the reasonableness review, and can committee members be involved in review?**

The Final Rule charges the OPTN with releasing data, so it is within the purview of UNOS staff, as the OPTN Contractor, to fulfill this obligation. In order to ensure consistency in the review process, it will be staff, and not members of the committee, who evaluate data requests.

- **How will the OPTN Contractor prevent potential misuse of data?**

Potential misuse of OPTN data is an inherent risk with releasing any data. This risk existed before this proposal, and is not increased by this proposal. The data use agreement attempts to restrict misuse of the data to the extent permissible by law.

- **Will the OPTN Contractor provide notice or a copy of the data file to members whose data have been requested?**

It would be impractical to send notice to every institution every time the OPTN Contractor provides a data file that contains institution identifiers. Additionally, the OPTN Contractor generally does not share researchers' unpublished research ideas, which is frequently the basis for such requests.

- **Will the OPTN Contractor release transplant hospital- or OPO-identified data if the data file contains easily patient-identifiable data?**

Currently, even without institution identifiers in the STAR file, it is possible to identify certain individuals. This has always been a potential problem, and it exists with any dataset that contains rare events that make the news. The key is that the requestor has to sign a data use agreement promising not to try to identify individuals.

- **Will this proposal permit recipients to obtain data about their organ donor from the OPTN?**

The OPTN Contractor provides candidates and recipients with their own medical records, and the donor information is not part of their medical records.

- **Remove “and state” from the policy, because the OPTN is governed by federal law, and it is impractical for the OPTN to ensure it is abiding by all state laws, and is governed by federal law.**

The policy language references “other applicable federal and state laws” to assure the community that the OPTN Contractor is bound by the Privacy Act and HIPAA, and other applicable state privacy laws related to the disclosure of data. The policy language neutrally refers to the “OPTN Contractor” instead of UNOS, which is how all OPTN policies are constructed in the event that the OPTN Contractor changes in the future. In addition to federal laws, the OPTN Contractor has data disclosure obligations under state law. The current OPTN Contractor is situated in Virginia, and therefore the state laws “applicable” to the current OPTN Contractor are the laws of Virginia, not the laws of all 50 states.

- **What additional OPO data will be released outside of what is currently released by the OPTN and SRTR?**

Current policy allows the OPTN to release only a limited number of data fields by OPO (e.g., number of deceased donors in each OPO). The proposed policy will allow the OPTN to release any releasable OPTN data by OPO. For example, the OPTN will now be able to release, by OPO, the number and percent of kidney transplants from donors recovered by the OPO that were transplanted locally, regionally and nationally.

- **Will this proposal improve the process for OPOs to obtain information?**

This proposal does not impact OPOs' ability to obtain information about outcomes of specific organs. There is a report in Secure EnterpriseSM that provides all offers an OPO made for accepted organs, along with their outcomes. Additionally, there is a report in UNetSM that provides the most recent patient and graft status information for all transplanted organs the OPO recovered. OPOs also can request this information from the OPTN Contractor through a data request.

Which populations are impacted by this proposal?

This proposal affects the release of all OPTN data and therefore affects all candidates, recipients, donors, and OPTN members whose data reside in the OPTN database. Individuals, such as researchers, who request data will have access to more transplant hospital- and OPO-identified data than before. All requests for such data will follow the publicly posted Standard Operating Procedures for Review of OPTN Data Requests.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This proposal makes OPTN policy consistent with the requirements of the Final Rule.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

OPTN staff will provide DAC regular updates on whether the revised policy language and standard operating procedures for OPTN data requests have been sufficient for processing all requests for OPTN data received by the OPTN.

How will members implement this proposal?

Members will not need to do anything to comply with this policy. Both members and the public will have access to more OPTN data. The process for requesting institution-identified OPTN data will be publicly available in the Standard Operating Procedures for Review of OPTN Data Requests.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

Members will not need to do anything to comply with this policy and will not be evaluated for compliance with the policy.

Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

RESOLVED, that changes to Policies 19: Data Release; 19.1: Mailing Lists; 19.2: Composite Demographic Data; 19.3: Organ Center Data; 19.4: Sharing Arrangements; 19.5: Members; 19.6: Public Release of Transplant Hospital and OPO Activity; 19.7: Release of Transplant Hospital Specific Data; 19.8: Review of Member Specific Data; 19.9: Access to Recipient Outcomes Data; 19.10: Information before the Board of Directors; 19.11: Release of Human Leukocyte Antigen (HLA) Type of a Recipient's Prior Donor; 19.12: Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier; 19.13: Access to Database; 19.14: Transfer of Information; 19.15: Specific Projects; 19.16: Public Use, Presentations, and Publications; and 19.17: Committee Access to Data, as set forth below, are hereby approved, effective March 1, 2016.

Policy 19: Data Release

The OPTN Contractor will release OPTN data according to the Final Rule and other applicable federal and state laws and regulations. The OPTN Contractor will release all OPTN data requested by the Secretary of the Department of Health and Human Services (HHS).

~~19.1 Mailing Lists~~

~~Lists showing members' or program directors' names with addresses or telephone numbers may be released, only if both of the following requirements are met:~~

- ~~1. The Executive Director deems the request to be for a legitimate, non-commercial purpose furthering the objectives of the OPTN.~~
- ~~2. The OPTN Contractor receives an executed agreement restricting the use of the information for the permitted purpose.~~

~~19.2 Composite Demographic Data~~

~~The OPTN Contractor may release to the public any composite demographic national, regional, or state data that is provided to HRSA through the OPTN Contract, such as the following:~~

- ~~• The number of transplant recipients, according to organ type, ethnicity, blood type, gender, and age~~
- ~~• The number of candidates on the Waiting List according to organ type, ethnicity, blood type, gender, and age~~
- ~~• The number and outcome of organs recovered~~

~~19.3 Organ Center Data~~

~~The OPTN Contractor may release to the public composite Organ Center information such as the following:~~

- ~~• The number of organs allocated through the Organ Center~~
- ~~• Data reflecting Organ Center activity~~
- ~~• The number and final destination of kidneys placed internationally through the Organ Center~~

19.4 Sharing Arrangements

The OPTN Contractor may release to the public the names of members participating in sharing arrangements approved by the Board of Directors.

19.5 Members

The OPTN Contractor may release to the public listings of members (including names of personnel).

19.6 Public Release of Transplant Hospital and OPO Activity

The OPTN Contractor may release to the public, without obtaining permission from each member, the analysis results containing the following data:

1. Updated transplant hospital-specific waiting list activity, by organ type, including but not limited to the number of candidates on the waiting list at the initiation of a period; the number of candidates added to the list; and the number of candidates removed from the list for death, transplant, and other reasons and, to the extent relevant to the organ type, the probability of survival on the waiting list within a specific period of time stratified by demographic and medical factors as determined appropriate by the Policy Oversight Committee (POC). These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.
2. Updated transplant hospital-specific waiting list size, by organ type, stratified by demographic and medical factors as determined appropriate by the POC.
3. Updated transplant hospital-specific or OPO-specific waiting time information, by organ type, stratified by demographic and medical variables as determined appropriate by the POC, and the probability of receiving a transplant within a specific period of time stratified by demographic and medical factors as determined appropriate by the POC.
4. Updated transplant hospital-specific risk adjusted survival rate information, along with percentage of transplants with follow up information, using data that may be validated by the member through the OPTN Contractor, by organ type, assessing transplants performed during a period that allows the OPTN Contractor sufficient time to collect the data and compute the rates as determined by the POC. The adjusted, transplant hospital-specific survival rate information may include, to the extent relevant to the organ type, the probability of survival pre-transplant, post-transplant and the probability of survival with or without a transplant. An appropriate period of analysis also will be determined by the POC.
5. Updated transplant hospital-validated transplant volumes as may be validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors as determined appropriate by the POC. These data may be presented on a calendar year basis and for such portions of the calendar year as determined by the POC. At a minimum, the OPTN Contractor may release the following transplant hospital volume information:
 - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients of a particular age.
 - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, for recipients with a particular diagnosis.
 - Transplant hospital-specific transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
 - Transplant hospital-specific multi-organ transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor.
 - Transplant hospital-specific non-resident alien transplant volume, by year, by organ type, using data that may be validated by the member through the OPTN Contractor, by deceased and living donor transplant.
 - Transplant hospital-specific waiting list size on any given day, by organ type, according to the waiting list.

- ~~OPO-specific data on the number of non-U.S. citizen organ donors, by year and by organ type, using data that may be validated by the members through the OPTN Contractor.~~
- ~~Transplant hospital- and OPO-specific data submission compliance rates.~~
- ~~Updated OPO-specific donor procurement volumes, using data validated by the member through the OPTN Contractor, including organ-specific authorization, procurement, and utilization volumes, by OPO; and numbers of donors by OPO, using data validated by the member through the OPTN Contractor, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.~~
- ~~Updated OPO-specific organ transplant volume, using data validated by the member through the OPTN Contractor, showing number of organs procured, number of organs imported into the OPO, and number of organs exported from the OPO. These data may be presented on a calendar year basis and for such portions of a calendar year as determined by the POC.~~
- ~~OPO-specific organ transplant volume and size of waiting list, using data validated by the member through the OPTN Contractor, by organ type, stratified by demographic and medical factors for such period(s) as determined appropriate by the POC.~~
- ~~Transplant hospital, OPO, or other organization-specific data as approved by the Executive Committee, which the OPTN anticipates will be otherwise duly released by the Department of Health and Human Services (HHS) to the public, together with such explanatory or other text or material as the Executive Committee deems appropriate to assist readers in understanding the data.~~

~~19.7 Release of Transplant Hospital Specific Data~~

~~The OPTN Contractor may release to OPO members such transplant hospital specific data as are required for the OPOs to prepare reports or other documents required by the OPTN for the purposes of assessing the impact of variances, alternative local units and sharing agreements on organ allocation.~~

~~19.8 Review of Member Specific Data~~

~~During the data validation process, the OPTN Contractor may release to members for their review such primary data as may be needed for member-specific reports for public release. For example, donor and histocompatibility data about transplants performed at a transplant hospital may be sent to that transplant hospital for review (but not for modification without instruction to the OPTN Contractor by the original institution submitters). Conversely, for these purposes, laboratories and OPOs may receive relevant data submitted to the OPTN Contractor by transplant hospitals. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions.~~

~~19.9 Access to Recipient Outcomes Data~~

~~OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness of deceased donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the OPTN Contractor. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions. These data fields are located on the *Transplant Recipient Registration* forms and include all of the following:~~

~~Recipient status (all organs)~~

- ~~Living—date of hospital report~~
- ~~Dead—date and cause of death~~
- ~~Re-transplanted prior to hospital discharge—date~~
- ~~Cause of retransplant (thoracic only)~~

~~Clinical information at discharge (kidneys only)~~

- Most recent serum creatinine prior to discharge
- Did kidney produce >40 mL of urine in first 24 hours?
- Did recipient need dialysis within first week?
- Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?

Transplanted kidney, liver or pancreas status at discharge

- Functioning or failed
- If failed, date and cause
- Preservation Information (all organs)

19.10 Information Brought before the Board of Directors

The OPTN Contractor may release to the public any information brought before the Board of Directors in public sessions.

19.11 Release of Human Leukocyte Antigen (HLA) Type of a Recipient's Prior Donor

The OPTN Contractor may release a recipient's prior donor's HLA type to a transplant hospital if the recipient is under that transplant hospital's care, or to the laboratory that provides services to that transplant hospital, without obtaining permission from the transplant hospital that performed the original transplant or the laboratory that performed the donor's typing.

19.12 Release of HLA Type of Donors and Recipients with Laboratory Name and Identifier

The OPTN Contractor may release, without obtaining permission from each member laboratory, the HLA type of deceased donors and recipients with the name and identifier of the laboratory that performed the typing to member laboratories for the purpose of resolving discrepant donor and recipient HLA typing results as set out in *Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results*.

19.13 Access to Database

Only OPTN Contractor staff, or individuals engaged by or adjunct to Contractor staff who are bound by contracts that prohibit competing interests and breaches of confidentiality, will be permitted to program or have direct access to data within the OPTN computer match program, or waiting list, or maintained in any other form. Members requesting access to data regarding their own candidates and recipients will be provided access to that information when practicable as determined by the OPTN Project Director. Unless permitted elsewhere in policy, neither individuals nor members will be given access to individual candidate, recipient, or member-specific information other than that from their own organization, without prior written approval from those individuals or members identified. Candidate, recipient, and institution-identified data will be made available to the Scientific Registry for Transplant Recipients (SRTT) Contractor.

19.14 Transfer of Information

All requests for data should be made through the Data Request System. Requests involving twenty hours or more of programming time or any statistical analyses that are considered to be extensive may be subject to the additional requirements in *Policy 19.15: Specific Projects*.

Unless permitted by this Policy, data will be provided with the deletion of all candidate, recipient and transplant hospital specific identifying information. Comprehensive datasets with transplant hospital and candidate and recipient identifying information encrypted may be given out for research purposes with the approval of the POC.

Under some circumstances, transplant hospital specific data (standard analysis files) not otherwise releasable may be provided to bona fide researchers, subject to the approval of the POC using as guidance the Agreement for Release of Data, as approved by the POC. In order to obtain these data, the submitting individual must meet the conditions for their release and sign an Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis.

Use of such data must meet the requirements of *Policy 19.16: Public Use, Presentations, and Publications*.

As required by the OPTN contract, the OPTN Contractor may release records which are identifiable as to candidate, recipient, transplant hospital or OPO without a signed Agreement for Release of Data only pursuant to official requests for data from the Department of Health and Human Services in accordance with federal or state laws and regulations.

19.15 Specific Projects

Any individual or group requesting data requiring twenty or more hours of programming time and/or any statistical analysis of a specific question by the OPTN Contractor staff may be asked to submit a written concept paper to the POC. The POC (its chair plus representative committee members) will vote to approve or disapprove each request, and may also prioritize approved requests, based on scientific or clinical merit, importance to the OPTN, and the potential ability to address the question. The approval and priority status of each request will be provided to the submitting individual. Upon approval, the submitting individual will be notified of the OPTN Contractor staff assigned to complete the request. The submitting individual must indicate to the assigned staff whether he/she wishes to be directly involved in the analysis and the project work group.

Data will be provided with the deletion of all candidate and recipient specific identifying information. Transplant hospital identifiers may be provided to bona fide researchers who meet the conditions specified in Agreement for Release of Data, which sets forth confidentiality and security stipulations for the data's release and use. Such data may be provided on a cost reimbursement basis. Use of such data will require written acknowledgment of the source of the data and the date it was provided, as required by *Policy 19.16: Public Use, Presentations, and Publications*.

19.16 Public Use, Presentations, and Publications

All scientific data provided and/or analyses performed by the OPTN Contractor utilizing data collected for the OPTN must adhere to the following specific requirements regarding approval, content, confidentiality, and authorship.

19.16.A Public Use or Presentation of Specific Projects or Studies

The scientific and analytical content of all abstracts or manuscripts developed from customized data requests, comprehensive encrypted datasets, or standard analysis files must be approved by the POC and any ad hoc work group appointed by that Committee prior to their public presentation or publication. If the analysis has not been provided prior to release by the investigator or institution, the OPTN Contractor cannot assume responsibility for the correctness of the findings or interpretations. Failure to include the OPTN Contractor in pre-release preparation may be an adverse consideration in subsequent applications by the investigator or

institution for additional data. Any contractor staff that makes a significant intellectual contribution to a study abstract, presentation, or manuscript should be offered the opportunity to be included as an author. Contractor staff may not be listed as study authors without obtaining written permission from the appropriate staff. A copy of all published abstracts, manuscripts, or news releases should be submitted to staff and/or the POC for informational purposes as soon as practicable.

19.16.B Data Obtained Through the Data Request System

Abstracts and manuscripts prepared using routinely available data obtained through the data request system do not require approval by the POC. Routinely available data will comprise all of the following:

1. Data provided in regularly updated standard reports
2. Data requested by OPTN members regarding their own institution or candidates and recipients
3. Data requested by the Department of Health and Human Services

However, the source and date of the data obtained must be acknowledged in text or graphic presentations. A copy of each published abstract, manuscript, or news release should be submitted to OPTN Contractor and/or the POC for informational purposes as soon as practicable. Publications that use data collected for the OPTN will include the following notice: *The data reported here have been supplied by [XXX], the OPTN Contractor. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official Policy or interpretation of the OPTN, or the U.S. Government.*

19.17 Committee Access to Data

Confidential Information, as herein defined, will not be made available in a public meeting. In a non-public forum or meeting setting, access to Confidential Information will be limited to members of the Board of Directors, members of permanent standing or ad hoc committees, OPTN Contractor staff and individuals engaged as an adjunct to Contractor staff. Access will be limited to the above described individuals, provided that these individuals are performing functions on behalf of the OPTN and are either bound by a fiduciary responsibility to the OPTN or a contractual obligation to the OPTN Contractor to maintain the confidentiality of such data and information. These individuals will have no ownership right in or to any of the Confidential Information and maintenance of the Confidential Information will be a private and confidential matter which is required for the continued success of the OPTN and its business. This Confidential Information includes but is not limited to financial data and information; data and information relating to procedural and substantive needs, problems, developments and projects; and data and information regarding deceased and living organ donors and recipients and institutions and medical personnel involved in organ transplantation, which constitute sensitive medical data or information subject to federal or state confidentiality statutes and regulations, all of which constitute trade secrets or confidential information of the OPTN. All such data and information together with business practices and procedures of the OPTN will be referred to collectively as "Confidential Information."

At such time as it becomes necessary to present or review candidate and recipient specific or transplant hospital specific data or other Confidential Information, such data or Confidential Information will be provided in individual packets for review at that non-public meeting only. At the conclusion of the meeting all individual packets will be collected by the administrative staff, and no such data or Confidential Information will be permitted outside the meeting room except that maintained by administrative staff and adjunct personnel. When practicable, the Confidential Information will be displayed electronically via overhead projection or slide projection for discussion purposes thereby eliminating the need for individualized sets of the Confidential Information. Only OPTN Contractor staff, or government staff pursuant to contractual requirements, will be able to retain the data or Confidential Information in written or electronic form.

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297 ~~In no event will any person, other than OPTN Contractor staff and adjunct personnel in attendance in any~~
298 ~~non-public meeting be permitted to have access to these data or confidential information outside the~~
299 ~~meeting room. Cooperation and compliance with these procedures will ensure the integrity of the OPTN~~
300 ~~and foster the trust of those who are associated with or who have dealings with the OPTN.~~
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Appendix A

Standard Operating Procedures for Review of OPTN Data Requests

Requests for Transplant Hospital or OPO-Identified Data

The OPTN Contractor will release transplant hospital and OPO-identified data according to the following table:

Release of Transplant Hospital- and OPO-Identified Data by the OPTN Contractor

If the request is for...	Then the OPTN Contractor will...
Confidential or peer reviewed data	Not release the data
A standard dataset, such as a STAR file	Release the data
A customized dataset	Release the data, as staff time and resources permit
A significantly customized dataset	Release the data if staff time and resources permit and if the requestor is willing to pay a reasonable fee

Requests for Person-Identified Data

The OPTN Contractor may release person-identified data according to the following table.

Release of Person-Identified Data by the OPTN Contractor

If the requestor is...	Then the OPTN Contractor may release the following person-identified data:
An individual	Data pertaining to that individual
Anyone granted authorization to receive information about an individual	Data pertaining to that individual
A member	<ul style="list-style-type: none"> • Data previously submitted by that member to the OPTN Contractor • Data that are necessary for that member to prepare a report required by the OPTN Contractor • Data that enable the OPTN Contractor to fulfill its obligations under the OPTN contract
An OPO	Recipient characteristics and outcomes data for each transplanted organ that was recovered by that OPO

If the requestor is...	Then the OPTN Contractor may release the following person-identified data:
A transplant hospital	<ul style="list-style-type: none"> • Recipient characteristics and outcomes for each organ offer received by that transplant program • Whether the transplant program's candidate is registered on the waiting list at more than one transplant program, according to <i>Policy 3.4.G: Multiple Transplant Program Registrations</i>
A transplant hospital or its affiliated histocompatibility laboratory	Prior donor's HLA information for any recipients under that transplant program's care
A histocompatibility laboratory	HLA information of deceased donors and recipients typed by that laboratory when discrepant HLA information is reported to the OPTN Contractor
Anyone authorized to receive data, according to federal laws and regulations	Data approved by the U.S. Department of Health and Human Services (HHS), according to federal laws and regulations

Requests for Person-Level De-Identified Data (e.g., STAR files)

Before receiving person-level de-identified data from the OPTN Contractor, requestors must submit a signed data use agreement (DUA) to the OPTN Contractor. The DUA must contain *both* of the following agreements:

1. The requestor agrees to neither attempt, nor permit others to attempt, to learn the identity of any person whose information is contained in the data.
2. The requestor agrees to include the disclaimer in the signed DUA in any publication using the released data.

Requests for Confidential Information

The OPTN Contractor will release confidential information if the following requirements are met:

Requirements for Release of Confidential Information

The requestor is at least <i>one</i> of the following:	And <i>both</i> of the following are true:
<ul style="list-style-type: none"> • Bound by a fiduciary responsibility to the OPTN Contractor • Contractually obligated to the OPTN Contractor to maintain the confidentiality of the released information • Acting on behalf of the OPTN Board of Directors • Acting on behalf of an OPTN Committee 	<ol style="list-style-type: none"> 1. The request is necessary to perform an OPTN function on behalf of the OPTN Board of Directors or an OPTN Committee 2. The OPTN Contractor approves the request

Requests for Personnel Information at Member Institutions

The OPTN Contractor will release contact information for personnel at member institutions only if *both* of the following requirements are met:

1. The requestor submits a signed data use agreement (DUA) to the OPTN Contractor.
2. The OPTN Contractor approves the request.